DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
2098 Gaither Road
Rockville, MD 20850

AUG 2 8 2006

WARNING LETTER

VIA FEDERAL EXPRESS

Mr. Jean-Chuan Lo
President
Chien Ti Enterprise Co., Ltd.
No. 33-12, Lin 1, Chiu Tou Village
Hsin Wu Hsaing, Taoyuan Hsien
Taiwan, Republic of China

Dear Mr. Lo:

During an inspection of your firm located in Taoyuan Hsien, Taiwan on April 17, 2006, through April 20, 2006, our investigator(s) determined that your firm manufactures mobility scooters and power chairs. These products are devices within the meaning of section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. § 321(h)).

This inspection revealed that these devices appear to be adulterated within the meaning of section 501(h) of the Act (21 U.S.C. § 351(h)), in that the methods used in, or the facilities or controls used for, their manufacture, packing, storage, or installation are not in conformity with the Current Good Manufacturing Practice (CGMP) requirements of the Quality System (QS) regulation found at Title 21, Code of Federal Regulations (CFR), Part 820. Significant violations include, but are not limited to, the following:

1. Failure to establish and maintain adequate procedures for the identification, documentation, validation or where appropriate verification, review, and approval of design changes before their implementation, as required by 21 CFR 820.30(i). For example:

   a) Your firm's HS-1000 design input document, dated 92-2-25 (2003-2-25), for the Power Chair stated that the load capacity is [redacted]. This did not match the current product specification of [redacted] load capacity. Further, the design input document specified a speed of [redacted] and this did not match the current product specification of [redacted]. Your firm does not have a design change document to support the changes in the product specifications.

   b) Your firm's Printed Circuit Board, Part Number [redacted], was modified in July 2005 with the addition of a resistor. This was not documented with an assembly drawing and approved until 95.04.17 (April 17, 2006).

   We received a response from Ms. Vivian Lo, Sales Manager, dated 5/31/2006 concerning our investigator's observations noted on the FDA 483. We have reviewed

your response and have concluded that it is inadequate because the firm's Product Modification Procedure, CT-P-0001, dated 4/27/2006 does not require validation of the change or provide criteria when verification alone is appropriate. The firm did not provide justification for not performing validation. In addition, the firm did not follow Product Modification Procedure, CT-P-0001, dated 4/27/2006 for the Printed Circuit Boards. The Modification Request Form was not provided. Your firm did not provide documentation showing that personnel had been adequately trained on the Design & Development Procedures, the Product Modification Procedures, and the Documentation Administration Procedures.

2. Failure to establish and maintain adequate procedures for rework to include retesting and reevaluation of the nonconforming product after rework and to ensure that the product meets its current approved specifications, as required by 21 CFR 820.90(b)(2). For example:

   a) Your firm's mobility scooter, HS-580 SN 06CDC0327, was reworked for a motor brake malfunction but the finished device inspection record did not document complete retesting and re-evaluation to ensure that the reworked product met current approved specifications.

   b) Your employees were not following Scooter Inspection Card Procedure, CT-R-0004 (Finished Device Test Procedures).

   We received a response from Ms. Vivian Lo, Sales Manager, dated 5/31/2006 concerning our investigator's observations noted on the FDA 483. We have reviewed your response and have concluded that it is inadequate. We acknowledge the revision of your Inspection and Testing Procedures and your training records for these revised procedures. However, the response is not adequate because your firm did not provide any evidence that you went back and reviewed device history records to ensure that there was not a related product problem or a larger quality system problem.

3. Failure to develop, conduct, control, and monitor production processes to ensure that a device conforms to its specifications, as required by 21 CFR 820.70(a). For example:

   a) Part number [redacted], robotic welding control specifications for wire feed rate tolerance, was specified to be [redacted] when the correct tolerance rate should have been [redacted].

   b) Your employees were not following Scooter Inspection Card Procedure, CT-R-0004 (Finished Device Test Procedures).

   We received a response from Ms. Vivian Lo, Sales Manager, dated 5/31/2006 concerning our investigator's observations noted on the FDA 483. We have reviewed your response and have concluded that it is inadequate. We acknowledge your revisions of the Working Standard for 541402-89500L to reflect the correct tolerance, the blank for the Working Standard has been modified to re-locate the column that shows the correct tolerance, and the complete Working Standard has been reviewed and signed by

the manager issuing department to prevent the problem. However, the response is not adequate because your firm did not provide documentation showing that personnel had been adequately trained on the revised Work Standard.

4. Failure to include, or refer to the location of, all specifications in the device master record, as required by 21 CFR 820.181(a).

   For example, the device master record lacked a parts list and schematics for printed circuit board part numbers [redacted] and [redacted]. Also, the assembly, drawing for part number [redacted] with the added resistor was not available until after the start of this inspection.

   We received a response from Ms. Vivian Lo, Sales Manager, dated 5/31/2006 concerning our investigator's observations noted on the FDA 483. We have reviewed your response and have concluded that it is not adequate because your firm did not provide documentation showing that personnel had been adequately trained on the Design & Development Procedures. The firm failed to provide a procedure or training on how document control would ensure all the necessary documents and records would be readily available.

5. Failure to ensure that each production run, lot, or batch of finished devices meets acceptance criteria, as required by 21 CFR 820.80(d).

   For example, finished device acceptance testing for the Power Chair, HS-1000 SN 06AHA0105, was signed off and accepted without performing the current load test. The finished device acceptance testing for the mobility scooter, HS-580 SN 06CDC0314, was signed off and accepted without performing the RMP test.

   We received a response from Ms. Vivian Lo, Sales Manager, dated 5/31/2006 concerning our investigator's observations noted on the FDA 483. We have reviewed your response and have concluded that it is inadequate. We acknowledge your revision of Inspection and Testing Procedure(s) and your training records to the revised procedure(s). However, the response is not adequate because there was no evidence provided that your firm reviewed previous testing records to ensure the problem had not occurred with other products. Further, there was no scientific evaluation of the effects of these missing tests on existing products.

Medical Device Reporting Regulation

Additionally, the above-stated inspection revealed that your devices are misbranded under section 502(t)(2) of the Act, 21 U.S.C 352(t)(2), in that your firm failed or refused to furnish any material or information required by or under section 519 of the Act, 21 U.S.C. 360i, respecting the device and 21 CFR Part 803 - Medical Device Reporting (MDR) regulation.

1. Failure to develop written MDR procedures, as required by 21 CFR 803.17.

We received a response from Ms. Vivian Lo, Sales Manager, dated 5/31/2006 concerning our investigator's observations noted on the FDA 483. We have reviewed your response and have concluded that it is inadequate. FDA acknowledges your firm prepared a MDR procedure which you provided to the Investigator prior to close of the inspection. However, all of the requirements of 21 CFR 803.17 have not been met, as described below:

"Medical Device manufacturers, importers, and user facilities are required to develop, maintain and implement written MDR procedures for the following:

(a) Internal systems that provide for:
   (1) Timely and effective identification, communication, and evaluation of events that my be subject to medical device reporting requirements;
   (2) A standardized review process/procedure for determining when an event meets the criteria for reporting under this part; and
   (3) Timely transmission of complete medical device reports to FDA and/or manufacturers;

(b) Documentation and record keeping requirements for:
   (1) Information that was evaluated to determine if an event was reportable;
   (2) All medical device reports and information submitted to FDA and manufacturers;
   (3) Any information that was evaluated for the purpose of preparing the submission of annual reports; and
   (4) Systems that ensure access to information that facilitates timely follow-up and inspection by FDA."

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure compliance with applicable laws and regulations administered by FDA. The specific violations noted in this letter and in the Inspectional Observations, Form FDA 483 (FDA 483), issued at the closeout of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You should investigate and determine the causes of the violations, and take prompt actions to correct the violations and to bring your products into compliance.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action, which may include detaining your devices without physical examination upon entry into the United States until the corrections are completed. Section 801(a) of the Act (21 U.S.C. § 381(a)).

Please notify this office in writing within fifteen (15) working days from the date you receive this letter, of the specific steps you have taken to correct the noted violations, including an explanation of how you plan to prevent these violations, or similar violations, from occurring again. Include all documentation of the corrective action you have taken. If you plan to make any corrections in the future, include those plans with your response to this

letter as well. If the documentation is not in English, please provide a translation to facilitate our review.

Your response should be sent to the Food and Drug Administration, Center for Devices and Radiological Health, Office of Compliance, Division of Enforcement B, Orthopedic, Physical Medicine and Anesthesiology Devices Branch, 2098 Gaither Road, Rockville, Maryland 20850 USA, to the attention of William MacFarland.

If you need help in understanding the contents of this letter, please contact William MacFarland at the above address or at (240) 276-0120 or FAX (240) 276-0129.

Sincerely yours,

for Timothy A. Ulatowski
Director
Office of Compliance
Center for Devices and
Radiological Health